June 3, 2015

The Honorable Lois Capps
United States House of Representatives
2231 Rayburn House Office Building
Washington, DC 20515

Re: 21st Century Cures Act and the inclusion of children and seniors in clinical trials

Dear Congresswoman Capps:

As members of the Patient, Consumer, and Public Health Coalition, which includes organizations representing patients, consumers, health professionals, and scientists, we have admired your work on behalf of improving the quality of public health. We read your May 14, 2015 statement of support for the 21st Century Cures Act, stating that it would result in more children and seniors in clinical trials. However, our analysis of the bill finds that it suggests but does not require the changes needed to ensure their inclusion in clinical trials. And, unfortunately, there are several provisions in the bill that would have the opposite effect.

Like you, we are glad that there is language included in H.R. 6 (21st Century Cures Act, Section 1083) that calls for the National Institutes of Health Director to convene a workshop of experts on
pediatric and geriatrics, provide guidelines, and make the findings of the workshop publicly available. However, the language does not mandate that more children and seniors will be included in clinical research, nor is there specific language anywhere in the bill that would do so.

We encourage you to take a leadership role on this issue by proposing an amendment to the 21st Century Cures Act when it reaches the House floor that would require that clinical trials include sufficient numbers of pediatric patients and patients over 65. The amendment should be focused on requiring such data for trials used as the basis of FDA approval decisions for drugs and devices that will be used by children and older adults. Currently, the FDA often approves drugs that are widely used in older adults and sometimes by children, without any evidence that they are safe and effective for either of those age groups.

On the contrary, various provisions suggest that drugs and medical devices be approved based on information that could easily exclude children, older adults, women, and ethnic and racial minorities. Specifically, provisions within section 2121 of H.R. 6 would allow for approval of new antimicrobial drugs tested only in a very small number of patients (a limited population) but could then be prescribed for all patients without clear evidence that it is beneficial for all patients. That would be harmful to the types of patients not in the target population, and especially children, seniors, and possibly also to women and racial and ethnic minorities.

Even more worrisome, the bill would provide an incentive for Medicare to pay for antibiotics approved for such targeted populations, even if the small studies did not include patients over 65. Patients over 65 metabolize drugs differently and may be more vulnerable to dangerous side effects, making the vague language in that provision especially dangerous. We would like to work with your staff to modify the language of that provision to protect Medicare patients.

As you are aware, children, seniors, racial and ethnic minorities, and women are often underrepresented in clinical trials, even when drugs, vaccines, and medical devices will be used primarily by those particular groups of patients. Without adequate representation of these populations in clinical trials, our children and seniors are at risk of being treated with drugs that could be ineffective, or worse, unsafe. The same is true for women and racial and ethnic minorities.

As you know, Congress understood the importance of ensuring that clinical trials be conducted in broad and diverse populations of patients when it passed the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). Section 907 of this act required the FDA to publish and provide to Congress a report about the current state of inclusion and participation of demographic subgroups, including sex, age, race, and ethnicity in clinical trials. This report was released in August 2014. However, the FDA’s report glossed over the fact that the numbers of women, seniors, and ethnic minorities included in most studies reviewed by the FDA were too small to determine whether the new medical products were safe and effective for those groups.

We would welcome the opportunity to work with your staff on an amendment that would require inclusion of children and patients over 65.

Sincerely,

American Medical Women’s Association
Annie Appleseed Project
Association for Pelvic Organ Prolapse Support
Center for Medical Consumers
Connecticut Center for Patient Safety
Jacobs Institute of Women’s Health
MRSA Survivors Network
National Center for Health Research
National Consumers League
National Organization for Women
National Physicians Alliance
National Women’s Health Network
Center for Science and Democracy, Union of Concerned Scientists
Women Heart
WoodyMatters

The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or at pb@center4research.org